ISSN: 2322 - 0902 (P) ISSN: 2322 - 0910 (O)



Research Article

COMPARATIVE STUDY OF THE RELATIVE EFFICACY OF *KUMKUMADI* CREAMS (WITH VARIOUS WATER AND OIL PHASE) FOR THEIR *VYANGAHAR* EFFECT

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ABSTRACT

The importance of beauty and personality is increasing now a day as it is a competitive era. Along with increased demand of beautification, the problems are also increasing which cause damage to beauty or personality due to changed life style and polluted atmosphere. Among the personality damaging disorder or dis-beautifying conditions, *Vyanga* is such a condition which affects the beauty as well as personality. Many people are suffering from *Vyanga* today, among them women are commonly found due to changes occurring during pregnancy and use of cosmetics supplements. *Vyanga* is a '*Kshudra Roga*' (skin disorder) affecting the skin for which many internal medicine and external applications are suggested in texts. Local application is more useful in skin disorders as it directly act on lesion. In the context of *Vyanga*, *Kumkumadi Taila* has been strongly suggested as it directly acts on the site of lesion and all its contents possess coloring and depigmentation properties.

Kumkumadi cream with different bases was given to total 38 patients registered divided in three groups for duration of one month. All the three creams were found significantly effective (p<0.01) on moisture content of skin, size of lesion, color of lesion, itching and burning sensation of lesion. Among three, *Kumkumadi* cream no.2 was found most effective with relief of 67.94% in treating disease *Vyanga*.

KEYWORDS: Vyanga, Kumkumadi Tail, Kshudraroga.

INTRODUCTION

Vyanga is a 'Kshudra Roga' which affects the skin. In Ayurvedic texts, so many remedies are described as internal medicine and external application for skin disorders. Local application is more useful in skin disorders as it directly act on lesion. India's cosmetics and toiletries industry is tipped to grow 27 percent over 2006-2011, according to Euromonitor^[1] due to the country's strong economic performance and youthful demographic structure.

Maharshi Charaka has grouped different herbs according to their effects such as Varnya, Keshya, and Vayasthapana etc. which add to the beauty of an individual^[2]. Many hygienic performances like *Abhyanga*, *Snana*, and *Lepa* etc. are stated to have beautification of the physique and the psyche also[3]. There are reference of some processes like Avaghatanam (constant stirring with ladle) and Samalodan (thorough mixing) which are used till date for cream preparation. Even in Sushruta Samhita, Acharya has emphasized the importance of cosmetics and perfumes in the daily routine for persons who are meticulous about their sound health. This text has laid down as many as 24 rules or guidelines concerning making ones toilet and the use of cosmetics[4]. He also mentioned various Lepas under Kshudrarogachikitsa^[5]. In Chakradatta some Mukha Kantikara, Mukha Saundaryakara etc. Lepas, various Oil and Ghrita for better complexion and to treat

the *Kshudra Rogas* are prescribed^[6]. Sharangadhara Samhita refers certain special *Lepas* useful in *Arunshika*, *Indralupta*, *Darunaka*, *Palita* etc., *Snanas* and *Udvartana* are for the purpose of improving the beauty.

In the context of *Vyanga*, *Kumkumadi Taila* has been strongly suggested in Ayurvedic classics. *Kumkumadi Taila* is one such preparation which is attracting a lot of attention now a day. It is an effective *Tailakalpana* and now being utilized by cosmetic companies. But it is quite difficult to apply oil on the face. So considering this point, in present study *Kumkumadi* Cream for local massage is selected for the management of the disease *Vyanga*.

MATERIAL AND METHODS

Aims and objectives

- 1. To ensure the preparation of safe and efficacious *Kumkumadi* creams using contents of *Kumkumadi Tailam*.
- 2. Analytical study of *Kumkumadi* creams according to parameters laid down by CCRAS.
- 3. To explore and compare clinically the effect of various *Kumkumadi* creams on the disease *Vyanga*.

Drug review

Kumkumadi Tail- It was considered as an important preparation by Acharya as even 3 types of *Kumkumadi Taila* is also given in few texts. *Kumkumadi Taila* was

mostly given in *Kshudrarogachikitsa*. Its common *Rogadhikar* is *Vyanga, Nilika, Vaivarnya, Palita, Vali, Tilakalaka, Pidika, Mukhakarshya, Dushcchaya* etc. The first textual reference by the name *Kumkumadi Taila* is quoted in Ashtang Hriduya^[7]. Later many Acharya quoted this Taila in there texts. Chakradutta describes 3 types^[8]. For *Vyangaher karma, Lepana Karma* (in the form cream) is selected here as per the indication by Acharya Sushruta^[9]. Acharya Charak has described *Lepana* as *"Sadyah Siddhi*"

Karaka" because external application plays a key role in the skin regime.

In the present study, after many pilot studies, three types of *Kumkumadi* creams were prepared namely

- a. *Kumkumadi* Cream No 1 (*Kwatha* as water phase + Modern base as oil phase)
- b. *Kumkumadi* Cream No 2 (Extract as water phase + Modern base as oil phase)
- c. *Kumkumadi* Cream No 3 (*Kumkumadi* oil + Modern base)

The constituent drugs of these preparations are tabulated below:

Table 1: Showing Main Ingredients of Formulations

Sr. No.	Drug	Botanical Name	Part Used	
1.	Kumkuma	Crocus sativus	Stigma	
2.	Laksha	Tachardia lacca	Resin	
3.	Rakta chandan	Pterocarpus santalinus	Heartwood	
4. Majishtha		Rubia cordifolia	Root	
5.	Yashtimadhu	Glycyrrhiza glabra	Root	

Table 2: Classification of Drugs According to Skin Caring Property

Sr.No.	Name of drug	Chemical constituent	
1.	Kumkuma	Lanoliec acid, Oleic acid, Palmitic acid	Depigmenting
			Emollient
2.	Laksha	Laccirin	Depigmenting
		http://ijapr.in	Emollient
3.	Rakta Chandana	Glycine, Palmiticacid	Emollient
		Jon	Depigmenting
4.	Manjistha	Manjisthin, Purpin, xanthopurpin	Colouring agent
5.	Yashtimadhu	Glycyrrhizine	Demulcent
		a la	Emollient

Table 3: Yavakuta Churna Preparations of Main Ingredients

S.No.	Sanskrit Name	Latin Name	Quantity
1.	Manjishta	Rubia cordifolia	200 gms
2. Yashtimadhu		Glycirriza glabra	200 gms
3.	Rakta Chandana	Pterocarpus santalinus	200 gms
4.	Laksha	Tachardia lacca	200 gms

Table 4: Kwatha Preparations of Main Ingredients

S.No.	Sanskrit Name	Latin Name	Quantity
1.	Manjistha	Rubia cordifolia	200 gms
2. Yashtimadhu		Glycirriza glabra	200 gms
3. Rakta Chandana		Pterocarpus santalinus	200 gms
4.	Laksha	Tachardia lacca	200 gms

Table 5: Showing the Modern Base

Sr. No.	Content	Quantity
1.	Stearic acid	74 gms
2.	Cetyl Alcohol	11 gms
3.	Olive Oil	10 gms
4.	Potassium hydroxide	6 gms
5.	Tankana	9 gms
6.	Methyl paraben	1 gms
7.	Rose perfume	1gms

ANALYTICAL STUDY

Table 6: Showing the Comparative Organoleptic Parameters of 3 Samples

S.No.	Parameters Kumkumadi cream 1		Kumkumadi cream 2	Kumkumadi cream 3	
1.	Colour Light orange		Light brown	Peach Colour	
2.	2. Odour Rose		Rose	Rose	
3.	3. Taste Bitter		Bitter	Bitter	
4.	. Consistency Semisolid		semisolid	Semisolid	

Table 7: Showing the Comparative Values of Physico Chemical Parameters of all Three Samples

Sr. No.	Parameters	Kumkumadi cream 1	Kumkumadi cream 2	Kumkumadi cream 3	
1.	рН	7.57		6.7	
2.	Total fatty matter	24.86%	24.81%	75.81%	
3.	Loss on drying	59.12%	48.65%	04.50%	
4.	Rancidity test	Negative	Negative	Negative	

Table 8: Showing Rf Values of the Three Samples

Values	Sample 1	Sample 2	Sample3
1 peak	0.06	0.06	0.06
2 peak	0.17	0.17	0.14
3 peak	0.36	0.36	0.31
4 peak	0.39	0.46	-
5 peak	0.49	0.52	-
6 peak	0.64	0.63	-

CLINICAL STUDY

I. Selection of Subjects

38 volunteers were taken from the premise of the institute. Healthy volunteers willing to participate in trial, without any further skin disease were selected. The individuals were divided into these groups:

Group 1 was given Kumkumadi Cream no. 1

Group 2 was given Kumkumadi Cream no. 2

Group 3 was given Kumkumadi Cream no. 3

II. Sampling Technique

The volunteers were selected irrespective of their age, sex, religion, occupation etc. and simple random sampling technique was followed for grouping them into 3 groups.

III. Exclusion criteria

The individuals excluded from the trial were

- 1. Volunteer above 60 years and below 16 years of age
- 2. With past and present history of any skin disease e.g. Psoriasis, Dermatitis, Vitiligo etc.
- 3. Person suffering from any bacterial or fungal infection or any skin infestation or are under medication with antibiotics and antifungal drugs.
- 4. Person having viral infection e.g. Herpes.
- 5. Pregnant or lactating women.
- 6. Immuno-deficient state.
- 7. Any history of allergy or hypersensitivity to creams or lotions.
- 8. Person with endocrinal disorders like Cushing's or Addison's disease, Acne etc.
- 9. Person with big or dark scars on face.

PLAN OF STUDY

All the volunteers selected for the clinical trial were studied in 3 groups. The volunteers were asked to apply the cream after washing their face with clean water and mild cleanser at night. They were directed to massage it on face until it is absorbed with upward and outwards strokes. Their skin types, skin condition and history were taken at that time. The Melasma on the face of the individual was recorded with the help of a digital camera so that even a slight change in the complexion could be traced.

50 Gms. *Kumkumadi* cream no 1, 2 and 3 has been given to the individual of group I, II and III respectively.

Duration of Therapy

Total duration of the therapy for each group was 30 days. Discontinuation of the creams was recommended if there is any sort of irritation or allergy caused by the drug or the individual is unable to follow the trial schedule due to ignorance or busy routine.

Assessment Criteria

The improvement provided by the therapy was assessed on the basis of classical signs & Symptoms. All the sings & Symptoms were assigned score depending upon their severity to assess the effect of the drugs objectively. The detail of which is as shown below.

1. Colour Score

- ❖ Light Brown 1
- Srown 2
- Dark brown 3
- ❖ Black 4
- Dark black 5

2. Size Score

♦ 0-1 cm 1

- ❖ 1-3 cm 2
- ❖ 3-6 cm 3
- **♦** >6 cm 4

When lesions or patches are multiple, the size of the largest lesion is taken into consideration.

3. Dry Skin (Rukshata/Kharata/Parushata) Score

- Normal 0
- Mild (Not seen but felt by touch) 1
- Moderate (Stretching of the skin that person feels) 2
- Severe (Visible dryness Chapping & hardness of the skin) 3

4. Oily Skin (Snigdhata) Score

- Normal 0
- Mild (Not seen but felt by touch) 1 No need to wash face frequently (only 1-2 times a day)
- Moderate (Oiliness is visible on skin) 2
 Need to wash face frequently (3-4 times a day)
- Severe (Excessive Oiliness) 3
 Formation of Acne
 Need to wash face more frequently (>4 times a day)

5. Kandu (Itching) Score

- ❖ No Itching 0
- Mild (Occasional itching but doesn't disturb routine activity) 1

- Moderate (frequent itching, disturbs routine activity) 2
 - Does not disturb sleep
- Severe (Frequent itching that disturbs routine activity) 3
 Disturbs sleep

6. Daha (Burning sensation) Score

- ❖ No Burning sensation 0
- Mild Burning sensation (Occasional burning sensation) 1
 - Mostly when patient undergoes to Sun exposure
- ❖ Moderate Burning sensation (Frequent burning sensation) 2
 - This increases when patient undergoes to Sun exposure
- Severe Burning sensation (Continuous burning sensation) 3
 - With or without sun exposure

Observations And Results

In the present study total 38 volunteers of *Vyanga* were registered for the treatment. Out of which, 31 volunteers completed the full duration of treatment, while 7 volunteers left the treatment at different stages. All the 31 volunteers of *Vyanga* were randomly divided into 3 groups viz.

- (1) Kumkumadi cream no 1
- (2) Kumkumadi cream no 2
- (3) Kumkumadicream no 3 group with following details.

Table 9: Patients Registered In Each Group

Group	No of regi <mark>ste</mark> red individual	LAMA	No of completed individual
Kumkumadi cream no 1 group A	14	03	11
Kumkumadi cream no 2 group B	12	02	10
Kumkumadi cream no 3 group C	12 DAPR	02	10
Total	38	07	31

Total bio-statistical data like age, sex etc. and the effect of the treatment on 31 volunteers of *Vyanga*, who completed the full course of the treatment are being presented under respective groups below:

RESULTS:

1. Effect of therapy on the colour of the lesion

Table 10: Showing Comparative effect of therapy on the colour of the lesion

Groups	B.T	Mean		D:c	% of	CD	CE	т	D
	N	BT	AT	—Dif.	Change	SD	SE	1	P
Group I	11	4.8	03.00	1.8	37.50	0.51	0.13	3.06	< 0.01
Group II	10	4.43	01.42	3.01	67.94	0.63	0.16	3.67	< 0.01
Group III	10	4.32	01.45	2.87	66.43	0.61	0.15	3.61	< 0.01

Colour of the lesion was fade up to 67.94% in Group II, 66.43% in Group III and 37.50% in Group I. All the values of Group II and III are statistically highly significant.

2. Effect Of The Therapy On The Size Of The Lesion

Table 11: Effect of the Therapy on The Size of the Lesion

	Table 11. Effect of the Therapy on the Beston									
Groups	N	Mean		D:cc	0/ - 6 D:66	CD	CE	т	n	
		BT	AT	Diff.	% of Diff.	SD	SE	l I	P	
Group I	11	2.46	01.01	1.45	11.50	0.13	0.10	2.06	<0.01	
Group II	10	3.09	01.54	1.55	57.94	0.63	0.16	3.57	<0.01	
Group III	10	2.64	01.45	1.19	56.43	0.61	0.15	3.75	<0.01	

The size of the lesion was reduced up to 57.94% in group II, 56.43% in group III and 11.50% in group I. The values of group II and group III are statistically highly significant.

3. Effect of Kumkumadi creams on the moisture of the skin

Table 12: Effect of Kumkumadi Creams on the Moisture of the Skin

Groups N	NI	Mean		D:6	% of	CD	CE	т	D
	IN .	BT	AT	Dif.	Change	SD	SE	1	P
Group I	11	1.12	0.267	0.853	76.16	0.370	0.13	4.56	<0.01
Group II	10	0.988	.153	0.835	85.51	0.353	0.139	7.05	<0.01
Group III	10	0.727	0.097	0.63	86.65	0.512	0.158	6.59	<0.01

Relief was found in all the groups which were statistically highly significant in group II and III (i.e. 85.51% and 86.65% resp.) while it was only significant in Group I (76.16%).

4. Effect of therapy on *Daha* (Burning sensation)

Table 13: Showing Incidence of Daha

Groups	N	Mean		D:6	0/ -f.Ch	CD	CE	T	D
		BT	AT	Dif.	% of Change	SD	SE	1	r
Group I	01	1.00	0.00	1	100	00	1	-	-

Only one patient was found who had a complaint of *Daha*. 100% relief was found within one week of treatment in group I.

5. Effect of therapy on Kandu(Itching)

Table 14: Showing Incidence of Kandu

Groups	N	Mean		D:f	0/ of Change	CD	CE	T	D
		BT	AT	Dif.	% of Change	3D	SE	1	r
Group I	01	1.00	0.00	1 of Ayu	100	00	-	-	-

Only one patient was found who had a complaint of *Kandu*. 100% relief was found within one week of treatment in group I.

DISCUSSION

Discussion on drug review

- 1. The drugs of *Kumkumadi Taila* are *Pittashamaka*, *Guru*, *Snigdha*, *Madhura*, *Tikatarasa* and almost pacifying *Virya* and *Vipaka*, thus making this combination ideal one.
- 2. Text *Rasarnava* has included four drugs of *Kumkumadi Taila* in *Raktashamakvarga*.
- 3. Among the five drugs; *Kumkum, Laksha* and *Rakta Chandana* are having *Varnya* effect (Depigmenting action).
- 4. Among the ingredients of *Kumkumadi* cream, four drugs i.e. *Kumkum, Laksha, Rakta Chandana* and *Yashtimadhu* are having emollient property.
- 5. Two drugs i.e. *Manjistha* and *Laksha* contains colouring agent. Thus *Kumkumadi* creams were selected as a Depigmenting agent, Emollient and enhancing beauty therapy.

Discussion of analytical study- In order to produce quality herbal formulations, it is essential to do validation of herbal materials and documentation. A standard is the numerical value which quantifies the parameters and thus quality and purity of a material. *Kumkumadi* creams made in a semisolid creamy consistency had rose odour and bitter taste. pH of cream 1 is 7.57, cream 2 is 7.64 and cream 3 is 6.7. Total fatty matter was 24.86%in cream1, 24.81% in cream 2 and 75.81% in cream 3. This may be due to varied amount of fatty content added in them. Similarly loss on drying was 59.12 % in cream 1, 48.65% in cream 2 and 04.50% in cream 3, which can be because of varied water content added in them. Rancidity test of

all the creams was negative showing that it was good for use in clinical trial.

Discussion of clinical study- Volunteers were divided in 3 groups. Group 1 was given *Kumkumadi* Cream no. 1, Group 2 was given *Kumkumadi* Cream no. 2 and Group 3 was given *Kumkumadi* Cream no. 3 respectively for 1 month trial. The volunteers were asked to apply the cream after washing their face with clean water and mild cleanser at night. They were directed to massage it on face until it is absorbed with upward and outwards strokes.

Discussion on effect of the therapy-

Regarding Moisture content of the skin

Relief was found in all the groups which were statistically highly significant in group II and III (i.e. 85.51% and 86.65% resp.) which indicates that drug was equally effective on oily and dry skin. It may be balancing the secretion of sebaceous glands of the skin. According to Ayurveda, it acts on *Bhrajaka Pitta* and *Bhrajakagni*. The normal status of *Bhrajakagni* keeps the skin in normal condition.

♦ Regarding size of the lesion

The size of the lesion was reduced up to 57.94% in group II, 56.43% in group III and 11.50% in group I. The values of group II and group III are statistically highly significant.

Regarding colour of the lesion

Statistically highly significant results were obtained in group II and III regarding colour of the lesion.

Regarding Kandu and Daha

Least patients had complaint of *Kandu* and *Daha*. The drug was very much effective and 100% relief was obtained within a week. But larger sample size is necessary to prove the above mentioned fact.

Overall effect of the therapy: The overall effect of therapy can be summed up as:

- 1. *Kumkumadi* cream no 2 was the best therapy amongst all for *Vyanga* with maximum relief of 67.94% showing significant results with p value (<0.01).
- 2. *Kumkumadi* cream no 3 made of *Kumkumadi Taila* is equally good with relief percentage of 66.43% and showing significant results with p value (<0.01).
- 3. *Kumkumadi* cream no 1 gave 37.50% relief and p value (<0.01) shows significant results.
- 4. Cream prepared by Soxhlet apparatus extraction proves better than the cream prepared by decoction method. Cream prepared with *Kumkumadi Taila* was equally good.
- 5. Maximum relief was seen in black coloured people, which was 65%. This was followed by dark black people with 45% relief. It shows that this treatment works better with dark complexion. This may be because colour changes occurring on dark skin are more apparent than on fairer skin.

CONCLUSION: To conclude the present work the final results found are –

- Chakradutta gave 3 types of Kumkumadi Taila out of which, third one is used in the thesis having only Kalkadravya taken 1 Karsha each, Taila 1 Kudava and Ajakshira 2 Kudava. There is no mention of Kwathadravyas. Kumkum is taken 1/16 of Taila hence making it cost effective.
- ♦ कुङ्कुमंकायकान्तिकृत्॥" (Dh. Ni.)
 - As facial cream it is useful in improving complexion. Other contents of *Kumkumadi* creams were Depigmenting agent, Emollient and enhancing beauty therapy.
- Kumkumadi cream 1 was made in vanishing cream form using decoction of main ingredients. Kumkumadi cream 2 was also made in Vanishing cream form using Soxhlet apparatus for extraction of main ingredients. Kumkumadi cream 3 was also made in vanishing cream form using Kumkumadi Taila as main ingredient.

Cite this article as:

Sharma Usha, Singh Preeti, Saxena G.K, Bohra Mohita. Comparative Study of the Relative Efficacy of Kumkumadi Creams (With Various Water and Oil Phase) for their Vyangahar Effect. International Journal of Ayurveda and Pharma Research. 2017;5(8):43-48.

Source of support: Nil, Conflict of interest: None Declared

- ♦ Kumkumadi Tailam and Kumkumadi creams can be formulated as per parameters laid down by CCRAS.
- ♦ Kumkumadi creams have effect on Vyanga disease.
- Kumkumadi cream no. 2 (made up with extract) contains more medicinal value than that of Kumkumadi cream no. 1 (made up of decoction) and works better. While Kumkumadi cream no. 3, which contains Kumkumadi oil proves as good as Kumkumadi cream no 2.

Though understanding of any concept and observing the facts in volunteers comprise the main part of any presentation, the critical analysis and interpretation of the clinical data available with the textual references is also important. So the data available can be reutilized for further studies, and to arrive at some definite conclusions.

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